Reynolds Medical Ltd.

510(k) Submission
CardioNavigator

510(k) Summary

(1) Submitter Information

Name: Reynolds Medical Ltd.

Address:

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John Tate Road
Hertford, Herts SG13 7NW
ENGLAND

Telephone Number: 44-1992-507700

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: April 3, 2001

(2) Name of Device

Trade Name: CardioNavigator
Common Name: Central Database for Cardiology Devices
Classification name: Computers and Software, Medical

(3) Equivalent legally-marketed devices.

GE Marquette Muse, K980495

(4) Description

CardioNavigator is a Cardiology Information Management System to be used to organise the acquisition of cardiological data as well as the storage of diagnostic data and results.

It is a software product intended to organize and manage the databases for compatible Reynolds monitoring products and to act as a "control panel" for these products. Some of the software that formerly was used with these devices has been transferred to sections of CardioNavigator. The program itself is supplied with all products.

The individual products, listed below, are all data-gathering devices used to collect cardiology patient data (ECG or blood pressure). These devices were previously sold with dedicated software programs that allow the devices to be set-up or configured both to program the devices, and to receive downloaded data from the devices and produce reports. In general, the dedicated programs also have a database uniquely for data from that device. As noted before, these dedicated databases are replaced by the CardioNavigator database.

CardioNavigator maintains a common cardiology database for the data collected by the compatible devices, and also permits the user to operate the various devices in a manner identical to the way they were operated as individual products. As a common database, CardioNavigator stores data collected from each patient in the section of the database dedicated to that patient. When used as a method for operating the device, the user selects the icon associated with the device. The user then sees the opening screen for the operation of that device, and all succeeding screens, as they were seen when the device was used with its dedicated program.

CardioNavigator has no capacity for analyzing electrocardiograms. When CardioNavigator is used with the Pathfinder Holter analysis program, the Pathfinder program is loaded into the same computer, and Pathfinder can be called by CardioNavigator, but there are no other links.

CardioNavigator can be used on a personal computer (PC) that meets specifications established by Reynolds. CardioNavigator will work with Reynolds products already owned by the user, or with new Reynolds products (included in the list of compatible products) that the user may purchase later.

CardioNavigator may only be used in the United States with devices currently cleared by the FDA. These are:

1. CardioCall Event recorder and CardioConnect download system, K972649
2. Reynolds Holter systems, including
   Lifecard CF Holter recorder, K001025
   Pathfinder Holter analysis System, K951902
3. Tracker NIBP2 ambulatory blood pressure measurement system, K003004

(5) Intended Use

CardioNavigator, a software product, is intended to organise the acquisition of cardiological data from Reynolds Medical monitoring products as well as the storage of

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diagnostic data and results. It is indicated when a user wishes to consolidate the databases of his Reynolds products.

(6) Performance Data

(a) Non-clinical tests

CardioNavigator has been extensively validated by itself and in conjunction with the associated Reynolds devices.

(b) Clinical tests

Clinical tests are not necessary, since CardioNavigator uses the same technology as the predicate device.

(c) Conclusions

CardioNavigator is equivalent in safety and efficacy to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2001

Reynolds Medical Ltd.
c/o Mr. George H. Myers
Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K011345
Trade Name: CardioNavigator Information Management System
Regulation Number: 21 CFR 870.2920
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: April 27, 2001
Received: May 2, 2001

Dear Mr. Myers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition,
FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you

might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K011345

Indications for Use Form

Device Name: CardioNavigator

Indications for Use:

CardioNavigator, a software product, is a computer program intended to organize and manage the databases for compatible Reynolds monitoring products and also to act as a "control panel" for these products. It is indicated when a user wishes to consolidate the databases of his Reynolds products.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the-Counter Use**
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011345